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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,547	07/19/2002	Patrick Camilleri	P32328	1624
20462	7590	03/09/2004		
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
			EXAMINER DESAI, ANAND U	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,547

Applicant(s)

CAMILLERI ET AL.

Examiner

Anand U Desai, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 20-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19 and 33 is/are rejected.
- 7) ☒ Claim(s) 2-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date December 12, 2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I drawn to claims 1-18 in Paper filed on February 5, 2004 is acknowledged. The traversal is on the ground(s) that the technical feature that links the inventions of Groups I, II, and III is the disclosed structure. This is not found persuasive because the technical feature linking Groups I-III is spermine:peptide based surfactant compounds, which does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL. However, pursuant to 37 CFR § 1.475 (d), examiner will consider claims 19 drawn to a method of using the compound of claim 1, and 33 drawn to a method of manufacturing the compound of claim 1, in addition to claims 1-18. Claim 32 was cancelled. Claims 20-31 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-19, and 33 are currently under examination.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed. The priority date is June 16, 1999.

Information Disclosure Statement

3. The information disclosure statement filed on December 12, 2001 is being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities:

On page 2, line 7 there is a space missing between the words both and *in vitro*. On page 5, line 19 there is a space missing between the words cell and *in vitro*. On page 5, line 21 the word "immunisation" appears to be "immunization". On page 18, line 4 the word "sheme" appears to be "scheme", on line 6, is "amide" meant to be "amine", and also on line 11, is "amine" meant to be "amide"? The designation "Life Technologies" should be "Invitrogen" throughout the specification, see for example page 16, line 25.

Appropriate correction is required.

Claim Objections

5. Claims 2-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

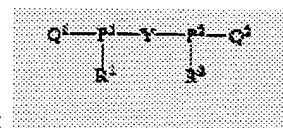
6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,693,167. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claims in the instant application are encompassed by claim 1 in U.S. Patent 6,693,167. Camilleri et al. disclose peptide-based gemini surfactant compounds. The peptide-



based gemini compound comprising two linked chains with the formula: , where Q^1 , or Q^2 is a positively charged hydrophilic head formed from one or more amino acids and/or amines, P^1 or P^2 a central portion having a polypeptide backbone, Y a linker, and R^1 or R^2 is a hydrophobic tail (see U.S. Patent '167, claim 1). Thus, the spermine:peptide-based surfactant compound described in claim 1 is encompassed by the gemini compound, when the Q^1 , and Q^2 hydrophilic heads are formed by the amino acid lysine, the linker, Y is an alkyl chain, and the R^1 , R^2 hydrophobic tail is a saturated hydrocarbon chain having up to 24 carbon atoms (current application, claim 1).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process of adding amino acids. How is the process of adding amino acids to a hydrocarbolyated spermine backbone completed?

Claim Rejections - 35 USC § 102

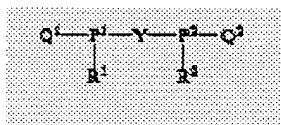
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

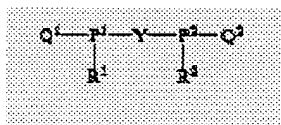
A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Camilleri et al. U.S. Patent 6,693,167 (Effective filing date=December 9, 1997). Camilleri et al. disclose peptide-based gemini surfactant compounds. The peptide-based gemini compound comprising



two linked chains with the formula: , where Q¹, or Q² is a positively charged hydrophilic head formed from one or more amino acids and/or amines, P¹ or P² a central portion having a polypeptide backbone, Y a linker, and R¹ or R² is a hydrophobic tail (see U.S. Patent '167, column 1, line 61 through column 2, line 8). Thus, the spermine:peptide-based

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surfactant compound described in claim 1 is encompassed by the gemini compound, when the Q^1 , and Q^2 hydrophilic heads are formed by the amino acid lysine, the linker, Y is an alkyl chain, and the R^1 , R^2 hydrophobic tail is a saturated hydrocarbon chain having up to 24 carbon atoms (current application, claim 1). Camilleri et al. also describe a method of transfecting eukaryotic, HEK 293 cells with a cationic peptide-based gemini compound and a recombinant DNA luciferase plasmid (see U.S. Patent '167, examples 17, and 18, columns 17-22, current application, claim 19).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

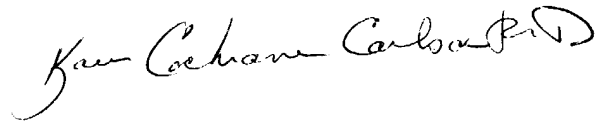
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (517) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 3, 2004

A handwritten signature in cursive script, likely belonging to an examiner or official.A handwritten signature in cursive script, reading "Karen Cochrane Carlson PhD".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER